

# **EXHIBIT 18**

**TESTIMONY OF  
THOMAS A. SCULLY  
ADMINISTRATOR  
CENTERS FOR MEDICARE & MEDICAID SERVICES  
ON  
REIMBURSEMENT & ACCESS TO PRESCRIPTION DRUGS  
UNDER MEDICARE PART B  
SENATE FINANCE COMMITTEE  
SUBCOMMITTEE ON HEALTH**

**March 14, 2002**

Chairman Rockefeller, Senator Snowe, distinguished Subcommittee members, thank you for inviting me to discuss Medicare payment for outpatient prescription drugs. As you know, prescription drugs have become an increasingly important component of modern health care, particularly for Medicare beneficiaries. The President has taken a number of steps to provide immediate relief to America's seniors and disabled from high drug costs, and we are continuing to work closely with Congress to modernize Medicare to include a comprehensive prescription drug benefit as we discussed at the hearing before this Committee just last week. It also is critically important, as the President's budget proposal provides, that we improve the payment system for the limited outpatient drugs that are now covered by Medicare. It is clear that this system, based on average wholesale price, or "AWP," is seriously flawed and I appreciate the Committee's interest in this issue. I look forward to working with you and your colleagues to ensure that Medicare and beneficiaries pay competitive prices for these prescription drugs and Medicare beneficiaries have access to the drugs they need.

Medicare pays more than many other purchasers for the drugs we cover because of Medicare's payment policies and the way that drug manufacturers report their prices. We all agree that Medicare should pay appropriately for all of Medicare's benefits, including the limited drugs the

**TESTIMONY OF  
THOMAS A. SCULLY  
ADMINISTRATOR  
CENTERS FOR MEDICARE & MEDICAID SERVICES  
ON  
REIMBURSEMENT & ACCESS TO PRESCRIPTION DRUGS  
UNDER MEDICARE PART B  
SENATE FINANCE COMMITTEE  
SUBCOMMITTEE ON HEALTH**

**March 14, 2002**

Chairman Rockefeller, Senator Snowe, distinguished Subcommittee members, thank you for inviting me to discuss Medicare payment for outpatient prescription drugs. As you know, prescription drugs have become an increasingly important component of modern health care, particularly for Medicare beneficiaries. The President has taken a number of steps to provide immediate relief to America's seniors and disabled from high drug costs, and we are continuing to work closely with Congress to modernize Medicare to include a comprehensive prescription drug benefit as we discussed at the hearing before this Committee just last week. It also is critically important, as the President's budget proposal provides, that we improve the payment system for the limited outpatient drugs that are now covered by Medicare. It is clear that this system, based on average wholesale price, or "AWP," is seriously flawed and I appreciate the Committee's interest in this issue. I look forward to working with you and your colleagues to ensure that Medicare and beneficiaries pay competitive prices for these prescription drugs and Medicare beneficiaries have access to the drugs they need.

Medicare pays more than many other purchasers for the drugs we cover because of Medicare's payment policies and the way that drug manufacturers report their prices. We all agree that Medicare should pay appropriately for all of Medicare's benefits, including the limited drugs the

program currently covers. The current system, which results in Medicare and beneficiaries paying excessive prices for certain prescription drugs, must be fixed. At the same time, we need to be certain that Medicare pays providers appropriately for their services when they furnish drugs to beneficiaries.

By law, Medicare does not pay for most outpatient prescription drugs. However, there are some specific exceptions where Medicare covers pharmaceuticals, such as those drugs that are not self-administered and furnished incident to a physician's covered services. In these cases, the law requires that Medicare pay physicians and other providers based on the lower of the billed charge or 95 percent of the drugs' AWP. Numerous studies have indicated that the industry's reported wholesale prices, the data on which Medicare drug payments are based, are vastly higher than the amounts drug manufacturers and wholesalers actually charge providers. That means Medicare beneficiaries, through their premiums and cost sharing, and U.S. taxpayers, are spending far more than the "average" price that we believe the law intended them to pay. Some affected physicians and providers have suggested that they need these Medicare "drug profits" to cross subsidize what they believe are inadequate Medicare payments for services related to furnishing the drugs, such as the administration of chemotherapy for cancer. A better approach is to pay appropriately for both the drugs and the services related to furnishing those drugs, and we need to take action this year to implement an appropriate payment system.

Clearly, Medicare drug pricing is complex. Over the years, numerous legislative efforts have made progress toward developing an effective alternative to AWP. These efforts have aimed at ensuring that Medicare and its beneficiaries do not pay more than they should for the limited number of

prescription drugs that Medicare covers, and that providers are compensated appropriately for their services. We continue to believe that an effective legislative remedy to this problem would be acceptable, and we intend to work with Congress to implement effective legislation. However, if necessary, we are prepared to build on the strong evidence and best ideas for reform developed in Congress by taking action under the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), which provided some authority for the Secretary to act after reviewing the General Accounting Office (GAO) report to Congress. Under BIPA, we could move to a market-based system for drugs and adjust payments for services related to furnishing drugs such as practice expenses for oncology administration. As we look to the future, particularly as we add broader prescription drug coverage to Medicare, it is even more important to develop market-based, competitive pricing systems for drugs so that we do not repeat the past mistakes of overpayment. We are committed to working with you, and all of Congress to ensure that Medicare pays appropriately for all benefits, including the limited drugs Medicare now covers.

#### **MEDICARE'S LIMITED DRUG BENEFIT**

The Centers for Medicare & Medicaid Services (CMS) pays most of the health care expenses of almost 40 million Medicare beneficiaries. If we were creating the Medicare program today, we would certainly include a prescription drug benefit. However, in 1965 when the Medicare program was enacted, prescription drugs played a less prominent role in health care than it does today. The emphasis in 1965 was on ensuring access to inpatient hospital care in Medicare Part A and providing access to physicians in Medicare Part B. Today, Medicare beneficiaries rely on prescription drugs as an integral part of their health care. Although by law, Medicare does not

generally cover over-the-counter or outpatient prescription drugs, Medicare does cover some drugs, including:

- Drugs that are not self-administered and furnished “incident to” a physician’s service, such as prostate cancer drugs;
- Certain self-administered oral cancer and anti-nausea drugs;
- Certain drugs used as part of durable medical equipment or infusion devices, (e.g., the albuterol that is put into nebulizers, which are devices used by asthma patients);
- Immunosuppressive drugs, which are used following organ transplants;
- Erythropoietin (EPO), far and away the drug Medicare spends the most money on, is used primarily to treat anemia in end stage renal disease patients and in cancer patients; and
- Osteoporosis drugs furnished to certain beneficiaries by home health agencies.

These drugs are typically provided in hospital outpatient settings, dialysis centers, or doctors’ offices, and are purchased directly by the physician or provider. Additionally, vaccines for diseases like influenza, pneumonia, and hepatitis are considered drugs and are covered by Medicare.

By law, we generally pay for these drugs based on the actual charge or 95 percent of the AWP, whichever is lower. This adds up to more than \$5 billion a year for currently covered drugs, approximately 80 percent of which is paid for from the Medicare Trust Funds. In general, Medicare beneficiaries must also share in the cost of purchasing these drugs through their Part B premiums, and except for the flu and pneumonia vaccines, the \$100 Part B annual deductible, and a 20 percent coinsurance.

**MEDICARE PAYMENT FOR CURRENTLY COVERED DRUGS**

The AWP is intended to represent the average price at which wholesalers sell drugs to their customers, which include physicians and pharmacies. Traditionally, AWP has been based on prices reported by drug manufacturers and published in compendia such as the *Red Book*, which is published by Medical Economics Company, Inc. However, manufacturers and wholesalers increasingly give physicians and providers competitive discounts that reduce the actual amount the physician or provider actually pays for the drugs. But Medicare's regulated payment system leaves the program behind in obtaining competitive discounts for drugs. These discounts are not reflected in the published price and reduce the amount providers actually pay to levels far below those prices published in the *Red Book*. Furthermore, use of the AWP, as reported by manufacturers to companies which compile such prices, creates a situation where a manufacturer can, for certain drugs, arbitrarily increase the reported AWP and, in turn, offer physicians a deeper "discount."

This Committee, CMS, the Department's Office of the Inspector General (IG), and others have long recognized the shortcomings of AWP as a way for Medicare to reimburse for drugs. The IG has published numerous reports showing that true competitive market prices for the top drugs billed to the Medicare program by physicians, independent dialysis facilities, and durable medical equipment suppliers were actually significantly less than the AWP reported in the *Red Book* and other publications. As competitive discounts have become widespread, the AWP mechanism has resulted in increasing payment distortions. However, Medicare has continued to pay for these drugs based on the reported AWP amount. The deep competitive discounts offered to physicians and providers by drug manufacturers, compared to the reported AWP, could give physicians and providers an incentive to use the manufacturer's products for Medicare beneficiaries. It is simply

unacceptable for Medicare to continue paying for drugs in an outdated, noncompetitive way that costs beneficiaries and the program far more than it should.

In the past, the Agency has attempted to remedy disparities between Medicare payments based on AWP and the amount actually paid competitively by physicians and providers. However, these efforts have not been successful. For example, the Agency's proposed June 1991 physician fee schedule included payments based on 85 percent of AWP. The Agency also proposed that certain very high volume drugs be reimbursed at levels equal to the lesser of 85 percent of AWP or the physician's or provider's estimated acquisition cost. The Agency received many comments, primarily from oncologists, indicating that an 85 percent standard was inappropriate. Most comments indicated that while many drugs could be purchased for less than 85 percent of AWP, other drugs were not discounted. Others suggested that while pharmacies and perhaps large practices could receive substantial discounts on their drug prices, individual physicians could not. As an alternative, beginning with 1992, a policy was established for Medicare to pay the AWP or the estimated acquisition cost, whichever was less.

Since the Estimated Acquisition Cost approach proved to be unworkable, subsequent legislation was proposed that would have required Medicare to pay physicians their actual acquisition cost for drugs. Under this proposal, physicians would tell Medicare what they paid for the drugs and be reimbursed that amount, rather than the Agency developing an estimate of acquisition costs and paying physicians based on that estimate. After considering this proposal, Congress adopted an alternative approach in the Balanced Budget Act of 1997 (BBA), setting Medicare's payment for drugs at the lesser of the billed charge or 95 percent of AWP. While this brought Medicare



payments closer to the prices that physicians and providers pay for drugs, Medicare payments were still significantly greater than the competitive discounts obtained by physicians. The system still tied Medicare payments to the artificially inflated industry-reported list prices. In fact, in a December 1997 report, the IG found payments based on AWP to be substantially greater than the prices available to the physician community. As an alternative to actual acquisition costs, Congress considered proposals to pay all Medicare drugs at 83 percent of AWP, a compromise between 95 percent of the AWP and the average discount found by the IG.

In May 2000, the Department of Justice (DOJ) and the National Association of Medicaid Fraud Control Units made accurate market wholesale prices for 49 drugs covered by Medicaid available to State Medicaid programs and to First Data Bank, a drug price compendium owned by the Hearst Corporation. These wholesale prices, culled from wholesale catalogs circulated among the provider community, reflected the actual Average Wholesale Prices for these drugs far more accurately than the drug manufacturers' AWP. In 2000, the Agency sent this new information to Medicare carriers and instructed them to consider these alternative wholesale prices as another source of AWP data in determining their January 1, 2001 quarterly update for many of these drugs. However, due to concerns about Medicare reimbursement for the administration of the chemotherapy and clotting factor drugs, the Administration instructed our carriers not to use the data for those drugs at that time. The Agency postponed Medicare carriers' use of the DOJ data, because in December 2000, Congress enacted the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act (BIPA), which established a moratorium on decreases in Medicare drug reimbursement rates, while the GAO conducted a study of Medicare drug pricing

and related payment issues. BIPA also provided some authority for the Secretary to address AWP after reviewing the GAO's findings.

As I stated, the Administration wants to work with Congress on a legislative remedy that benefits from competition in drug pricing. However, I am sure you will agree that needed improvements in Medicare's drug payment system are overdue, and the Administration is prepared to take action. Let me reiterate that we are committed to providing assistance to this Committee and Congress as you seek solutions to AWP and we look forward to working with you in the weeks ahead.

#### **CONCLUSION**

Medicare beneficiaries rely on prescription drugs, and the coinsurance they pay for covered drugs is tied directly to the prices that Medicare pays. We must find a competitive way to ensure that Medicare beneficiaries and taxpayers are no longer paying excessive prices for drugs that are far above the competitive discounts that are widely available today. We need to pay appropriately for all Medicare benefits, including the prescription drugs we cover and the services required to furnish those drugs. We look forward to working with you Mr. Chairman, this Committee, and the Congress to revise Medicare's payment policy for currently covered drugs. Thank you for the opportunity to discuss this important topic with you today, and I am happy to answer your questions.

###